EPA REGISTRATION NUMBER 66330-44 – Vol. 3

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 66330-UU

Send to SIG: check box ☐

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label
- ☒ Other: Technical Review

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Robert Westin

Phone: 305-5721 Division: RD/FB

Date: 11/22/06

Current as of Wednesday, March 01, 2006

5182925

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 28 2006

Laurent Mézin
Project Manager
Arysta LifeScience Corporation
15401 Weston Parkway, Suite 150
Cary, NC 27513

Subject: Iodomethane Technical
EPA File Symbol No. 66330-UU
Your submission dated August 15, 2005
EPA Decision No. 219256

Dear Dr. Mézin:

The Agency has determined that the 96 hour Acute Toxicity Test of Iodomethane with Common Carp (MRID 466234-01) is acceptable and satisfies the guideline requirement 72-1. A copy of the Agency's Product Data Review DP320700 dated November 21, 2006 is enclosed for your records.

The Agency's decision as to whether this product will be registered will be made upon completion of the review of other data submitted for this product.

If you have any questions, please contact Robert Westin by phone at (703) 305-5721 or via email at westin.robert@epa.gov.

Sincerely,

Mary L. Waller

Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505P)

Enclosure

PM 21

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PC Code: 000011
Data Review DP Barcode: 320700

DATE: November 21, 2006

MEMORANDUM

SUBJECT: Iodomethane Data Review

TO: Robert Westin, Risk Manager Reviewer
Mary Waller, Risk Manager 21
Cynthia Giles-Parker, Chief, Fungicide Branch
Registration Division (7505P)

FROM: James Felkel, Wildlife Biologist J. Felkel 11/21/06
Environmental Risk Branch V
Environmental Fate and Effects Division (7507P)

APPROVED BY: Mah T. Shamim, Branch Chief M. T. Shamim 11/21/06
Environmental Risk Branch V
Environmental Fate and Effects Division (7507P)

The attached document contains the Environmental Fate and Effects Division's (EFED) data review of a submitted acute freshwater fish study (MRID 466234-01). This study is currently classified as ACCEPTABLE.

CITATION: Sueta, S. 2003. A 96-hour Acute Toxicity Test of Iodomethane with Common Carp. Unpublished study performed by Kurume Laboratory, Fukuoka, Japan. Laboratory Report Number: 92548. Study submitted by Arysta LifeScience Corporation, Tokyo, Japan. Experimental start date was June 17, 2002 and experimental termination date was June 21, 2002. The final report was issued February 24, 2003.

EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, common carp, *Cyprinus carpio*, were exposed to Iodomethane at nominal concentrations of 0, 0.781, 1.09, 1.53, 2.14, and 3.00 mg ai/L under static renewal conditions. Measured concentrations were <LOD (<0.0500), 0.820, 1.08, 1.59, 2.07, and 3.05 mg ai/L (96.7-105% of nominal). During the 96-hour test, there were 28.6, 100, 100, and 100% mortalities in the 1.08, 1.59, 2.07, and 3.05 mg ai/L treatment groups, respectively. No other mortalities were observed. The sub-lethal effects included fish at the surface, complete loss of equilibrium, lethargic, and reduced activity in the ≥1.08 mg ai/L treatment groups. The NOAEC based on mortality and sub-lethal effects was 0.820 mg ai/L. The 96-h LC_{50} was 1.19 mg ai/L. Based on the results of this study, Iodomethane is categorized as moderately toxic to common carp on an acute toxicity basis in accordance with the classification system of the U.S. EPA.

This study is scientifically sound and it fulfills the US EPA guidelines for acute toxicity testing on freshwater fish. As a result, this study is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age (mean weight or length): Age not specified; 4.7 cm and 1.1 g (mean of 7 control fish at test termination).
Test Type (Flow-through, Static, Static Renewal): Static renewal

LC_{50}: 1.19 mg ai/L 95% C.I.: 0.82-1.59 mg ai/L
NOAEC: 0.820 mg ai/L Probit Slope: Not applicable
EC_{50}: Not calculated
Endpoint(s) Affected: Mortality and sub-lethal effects

Data Evaluation Report on the Acute Toxicity of Iodomethane to Common Carp

PMRA Submission Number {.....} EPA MRID Number 466234-01

Data Requirement:

PMRA Data Code	{.....}
EPA DP Barcode	D320700
OECD Data Point	{.....}
EPA MRID	466234-01
EPA Guideline	72-1

Test material: Iodomethane **Purity:** 99.9%
Common name: Iodomethane
Chemical name: IUPAC: Iodomethane or methyl iodide
CAS name: Iodomethane
CAS No.: 74-88-4
Synonyms: Not reported

Primary Reviewer: Rebecca Bryan **Signature:** Rebecca L. Bryan
Staff Scientist, Dynamac Corporation **Date:** 1/9/06

Secondary Reviewer: Teri S. Myers **Signature:** Teri S Myers
Senior Scientist, Cambridge Environmental Inc. **Date:** 1/19/06

Secondary Reviewer: J. Felkel
Wildlife Biologist, USEPA/OPP/EFED/ERB5 J. Felkel 11/21/06

Reference/Submission No.: {.....}

Company Code	{.....}	[For PMRA]
Active Code	{.....}	[For PMRA]
Use Site Category:	{.....}	[For PMRA]
EPA PC Code	000011	

Date Evaluation Completed: {dd-mm-yyyy}

CITATION: Sueta, S. 2003. A 96-hour Acute Toxicity Test of Iodomethane with Common Carp. Unpublished study performed by Kurume Laboratory, Fukuoka, Japan. Laboratory Report Number: 92548. Study submitted by Arysta LifeScience Corporation, Tokyo, Japan. Experimental start date was June 17, 2002 and experimental termination date was June 21, 2002. The final report was issued February 24, 2003.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to fish. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

This Data Evaluation Record may have been revised by the Environmental Fate and Effects Division subsequent to signing by Dynamac Corporation/Cambridge Environmental, Inc. personnel.

EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, common carp, *Cyprinus carpio*, were exposed to Iodomethane at nominal concentrations of 0, 0.781, 1.09, 1.53, 2.14, and 3.00 mg ai/L under static renewal conditions. Measured concentrations were <LOD (<0.0500), 0.820, 1.08, 1.59, 2.07, and 3.05 mg ai/L (96.7-105% of nominal). During the 96-hour test, there were 28.6, 100, 100, and 100% mortalities in the 1.08, 1.59, 2.07, and 3.05 mg ai/L treatment groups, respectively. No other mortalities were observed. The sub-lethal effects included fish at the surface, complete loss of equilibrium, lethargic, and reduced activity in the ≥1.08 mg ai/L treatment groups. The NOAEC based on mortality and sub-lethal effects was 0.820 mg ai/L. The 96-h LC_{50} was 1.19 mg ai/L. Based on the results of this study, Iodomethane is categorized as moderately toxic to common carp on an acute toxicity basis in accordance with the classification system of the U.S. EPA.

This study is scientifically sound and it fulfills the US EPA guidelines for acute toxicity testing on freshwater fish. As a result, this study is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age (mean weight or length): Age not specified; 4.7 cm and 1.1 g (mean of 7 control fish at test termination).
Test Type (Flow-through, Static, Static Renewal): Static renewal

LC_{50}: 1.19 mg ai/L 95% C.I.: 0.82-1.59 mg ai/L
NOAEC: 0.820 mg ai/L Probit Slope: Not applicable
EC_{50}: Not calculated
Endpoint(s) Affected: Mortality and sub-lethal effects

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the U.S. EPA OPPTS Guideline Number 850.1075. Deviations from U.S. EPA Guideline §72-1 included:

1. The species tested in this study, *Cyprinus carpio*, is not recommended by the US EPA §72-1 SEP guideline, but it is among species allowed by the draft OPPTS 850.1075 guideline (April 1996).
2. The age of the test organism at test initiation was not specified.
3. The acclimation period (9 days) was less than recommended (14 days). The food provided during acclimation was not reported.
4. There were only 7 fish per concentration; the reviewer calculated the biomass loading rate to be 0.33 g/L.
5. The TOC, particulate matter, and chlorine content of the water were not reported.

These deviations do not affect the acceptability or validity of the study.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Confidentiality statements were provided. This study was conducted in accordance with GLP standards set forth by the U.S. EPA (1989), (p. 3).

A. REPORTED MATERIALS:

1. Test material Iodomethane

Description: Colorless clear liquid

Lot No./Batch No. : 018801

Purity: 99.9%

Stability of compound under test conditions: The stability of the test substance in the dilution water during the course of the study was demonstrated by analytical determinations at 24 hour intervals for the "old" and "new" test solutions. Recoveries at all treatment levels were 93.0-118% of nominal concentrations during the test, with no pattern of decline.

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

Storage conditions of test chemicals: Test material was stored in a cool, dark place during the test period.

Physicochemical properties of Iodomethane.

Parameter	Values	Comments
Water solubility at 20EC	2 g/100 mL	
Vapor pressure	400 mmHG (25°C)	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

2. Test organism:

Species: Common carp, *Cyprinus carpio*
EPA recommends a cold water species (preferably rainbow trout Oncorhynchus mykiss) and a warm water species (preferably bluegill sunfish Lepomis macrochirus). OECD recommends choice of species at discretion of testing laboratory.

Age at test initiation: Age not specified

Weight at study initiation: 1.1 ± 0.17 g (mean of 7 control fish at test termination).
EPA recommends: mean 0.5 - 5 g.

Length at study initiation: 4.7 ± 0.20 cm (mean of 7 control fish at test termination).
EPA recommends: Longest not > 2x shortest; OECD recommends 2.0 ∀ 1.0 cm for bluegill and 5.0 ∀ 1.0 cm for rainbow trout

Source: Sugishima Fish Farm, Kumamoto, Japan
EPA recommends that all organisms be from the same source

B. REPORTED STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study
No range-finding study was reported.

b. Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation		The acclimation period was less than recommended. The food provided during acclimation was not reported.

Parameter	Details	Remarks *Criteria*
Period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	At least 9 days Same as test Not reported. Mortality was <5% during the 7 days prior to testing.	*The recommended acclimation period is a minimum of 14 days; OECD guideline recommends a minimum of 12 days. Pretest mortality should be < 3% 48 h. prior to testing. OECD pretest mortality criteria: >10% = rejection of entire batch; ≥ 5 and ≤ 10% = continued acclimation for 7 days; <5% = acceptable.*
Duration of the test	96 hours	*The recommended test duration is 96 hours.*
Test condition Static/flow-through Type of dilution system - for flow-through method. Renewal rate for static renewal	Static renewal Not applicable Every 24 hours	*A reproducible supply of toxicant is recommended. Consistent flow rate is usually 5-10 vol/24 hours; meter systems should be calibrated before and after study and checked twice daily during test period.*
Aeration, if any	No aeration during testing.	*Aeration is not recommended; OECD guideline recommends aeration. If aeration is necessary, test solutions must be analyzed periodically to verify exposure.*

Parameter	Details	Remarks *Criteria*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	 Glass tank 23 L Approximately 23 L	 *Test vessel size is usually 19 L (5 gal) or 30 x 60 x 30 cm. Fill volume is usually 15-30 L of solution.*
Source of dilution water Quality:	Dechlorinated tap water that was aerated prior to testing; water quality characterization was provided in Appendix 1, p. 28.	*Recommended source of dilution water is soft, reconstituted water or water from a natural source. EPA does not recommend the use of dechlorinated tap water; however, its use may be supportable if the biological responses for the organisms and chemical analyses of residual chlorine meet conditions in the Agency's 850.1010 guidelines for dilution water (http://www.epa.gov/opptsfrs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Draft/850.1010.pdf) Dilution water should be intensely aerated before the study. OECD permits dechlorinated tap water.*

Parameter	Details	Remarks *Criteria*
Water parameters: Hardness pH Dissolved oxygen Total Organic carbon Particulate Matter Metals Pesticides Chlorine Temperature {Salinity for marine or estuarine species} Intervals of water quality measurement	 44 mg/L 7.1-7.6 6.4-8.4 mg ai/L Not reported Not reported Not detected Not detected Not detected 22.8-23.0°C N/A Every 24 hours	The TOC, particulate matter, and chlorine content of the water were not reported. *Hardness:* *EPA recommends 40 - 48 mg ai/Las $CaCO_3$ (OECD recommends 10 - 250 mg a.i./L)* *pH:* *EPA recommends 7.2 - 7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes, monthly range < 0.8); (OECD recommends pH 6.0 - 8.5)* *Dissolved Oxygen:* *EPA recommends: Static: ∃ 60% during first 48 hrs and ∃ 40% during second 48 hrs; flow-through: ∃ 60%; (OECD guideline recommends at least 80% saturation value).* *Temperature:* *EPA recommends 12 EC for coldwater species, 17 or 22 EC for warmwater species, and 22 ± 1 EC for estuarine/marine organisms. (OECD recommends 21 - 25°C for bluegill and 13 - 17°C for rainbow trout).* *Salinity:* *EPA recommends 30-34‰ (parts per thousand) for marine, 10-17‰ for estuarine fish, weekly range < 6‰.* *Water quality should be measured at beginning of test and every 48 hours.*
Number of replicates/groups: control: solvent control: treated ones:	 1 Not applicable 1	 *Recommended number of replicates includes a control and five treatment levels. Each concentration should be 60% of the next highest concentration; concentrations should be in a geometric series.*
Number of organisms per replicate /groups: control: solvent control: treated ones:	 7 Not applicable 7	There were only 7 fish per concentration. *Number of organisms per replicate should be ∃ 10/concentration; OECD guideline recommends at least 7 fish/concentration.*

Parameter	Details	Remarks *Criteria*
Biomass loading rate	Not reported; reviewer calculated to be 0.33 g/L	1.1 g/fish * 7 fish/tank ÷ 23 L tank = 0.33 g/L *Recommended static conditions are # 0.8 g/L at # 17EC and # 0.5 g/L at > 17EC. Recommended flow-through conditions are # 1 g/L/day. OECD recommends a maximum of 1 g fish/L for static and semi-static, while higher rates are recommended for flow-through.*
Test concentrations: nominal: measured:	 0.781, 1.09, 1.53, 2.14, and 3.00 mg ai/L 0.820, 1.08, 1.59, 2.07, and 3.05 mg ai/L	
Solvent (type, percentage, if used)	N/A	*The solvent should not exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD recommends that the solvent not exceed 100 mg a.i./L.*
Lighting	16-hours light/8-hours dark	*The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period. OECD recommends a photo period of 12 -16 hours.*
Feeding	Animals were not fed during testing.	*Fish should not feed during the study.*
Recovery of chemical Frequency of determination Level of quantization Level of detection	93.0-118% of nominal Every 24 hours Not reported 0.0500 mg ai/L	Based on test samples (Table 5, p. 25).
Positive control {if used, indicate the chemical and concentrations}	Prior to testing, the 96-hour LC_{50} of CuSO4 5H2O was determined to be 0.257 mg/L for carp.	The reference substance test concentrations were not reported.
Other parameters, if any	None	

2. Observations:

Table 2: Observations

Parameter	Details	Remarks *Criteria*
Parameters measured including the sub-lethal effects/toxicity symptoms	Mortality and sub-lethal effects	
Observation intervals	Every 24 hours	*Observation intervals should be a minimum of every 24 hours.*
Were raw data included?	Yes, sufficient	
Other observations, if any	None	

II. RESULTS AND DISCUSSION:

A. REPORTED MORTALITY:

During the 96-hour test, there were 28.6, 100, 100, and 100% mortalities in the 1.08, 1.59, 2.07, and 3.05 mg ai/L treatment groups, respectively. No other mortalities were observed. The NOAEC based on mortality was 0.820 mg ai/L.

Table 3: Effect of Iodomethane on Mortality of Common carp.

Treatment (mg ai/L) measured and (nominal) concentration used	No. of fish at start of study	Observation period					
		Day 1		Day 2		Day 4	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Control (dilution water only)	7	0	0	0	0	0	0
0.820 (0.781)	7	0	0	0	0	0	0
1.08 (1.09)	7	0	0	0	0	2	28.6
1.59 (1.53)	7	0	0	0	0	7	100
2.07 (2.14)	7	0	0	4	57.1	7	100
3.05 (3.00)	7	0	0	7	100	7	100
NOAEC (mg ai/L)		3.05		1.59		0.820	
LC_{50} (mg ai/L)		>3.05		2.07[a]		1.18[a]	
Positive control, if used mortality: LC_{50}:		NA		NA		NA	

[a] Based on nominal test concentrations.
NA= Not applicable

B. REPORTED NON-LETHAL TOXICITY ENDPOINTS:

During the 96-hour test, the sub-lethal effects included fish at the surface, complete loss of equilibrium, lethargic, and reduced activity in the ≥1.09 mg ai/L treatment groups. The NOAEC based on sub-lethal effects was 0.820 mg ai/L.

Table 4: Sub-lethal Effect of Iodomethane on Common carp.

Treatment (mg ai/L) measured and (nominal) concentration used	Observation period		
	Day 1	Day 2	Day 4
	% affected[1]	% affected	% affected
Control (dilution water only)	N	N	N
0.820 (0.781)	N	N	N
1.08 (1.09)	N	N	Reduced activity
1.59 (1.53)	N	N	--
2.07 (2.14)	N	At the surface, lethargic, and reduced activity	--
3.05 (3.00)	Reduced activity	--[2]	--
NOAEC (mg ai/L)	2.07	1.59	0.820
LOAEC (mg ai/L)	3.05	2.07	1.08
EC_{50} (mg ai/L)	Not calculated	Not calculated	Not calculated
Positive control, if used % sub-lethal effect: EC_{50}:	NA	NA	NA

N = Appears normal
NA = Not applicable
[1] The % affected was not provided, only descriptions of the sub-lethal effects were reported.
[2] 100% mortality

C. REPORTED STATISTICS:

Method: The 96-hour LC_{50} was determined using the binomial test. The NOAEC was visually determined based on sub-lethal effects and mortality data. The calculations were based on the nominal test concentrations.

96-Hour
LC_{50}: 1.18 mg/L 95% C.I.: 0.781-1.53 mg/L
NOAEC: 0.820 mg/L
Probit Slope: Not provided 95% C.I.: Not applicable

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: The 96-hour LC_{50} was determined using the binomial method via TOXANAL statistical software. The NOAEC was visually determined based on sub-lethal effects and mortality data. The calculations were based on the mean-measured test concentrations.

LC_{50}: 1.19 mg ai/L 95% C.I.: 0.82-1.59 mg ai/L
NOAEC: 0.820 mg ai/L Probit Slope: Not applicable
EC_{50}: Not calculated
Endpoint(s) Affected: Mortality and sub-lethal effects

E. STUDY DEFICIENCIES:

There were no significant deviations from U.S. EPA guidelines that affected the acceptability of this study.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions regarding the LC_{50} estimate differed only slightly from the study author's; the reviewer's LC_{50} estimate was calculated using the mean-measured concentrations, instead of the nominal concentrations. As a result, the reviewer's LC_{50} is reported in the Executive Summary and Conclusions sections.

G. CONCLUSIONS:

This study is scientifically sound and it fulfills the U.S. EPA guideline for acute toxicity testing on freshwater fish. As a result, this study is classified as ACCEPTABLE. The 96-h LC_{50} was 1.19 mg ai/L. Based on the results of this study, Iodomethane is categorized as moderately toxic to common carp on an acute toxicity basis in accordance with the classification system of the U.S. EPA. The NOAEC for mortality and sub-lethal effects is 0.820 mg ai/L.

LC_{50}: 1.19 mg ai/L 95% C.I.: 0.82-1.59 mg ai/L
NOAEC: 0.820 mg ai/L Probit Slope: Not applicable
EC_{50}: Not calculated
Endpoint(s) Affected: Mortality and sub-lethal effects

III. REFERENCES:

No references were cited.

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

	EXPOSED	DEAD	DEAD	PROB.(PERCENT)
3.05	7	7	100	.78125
2.07	7	7	100	.78125
1.59	7	7	100	.78125
1.08	7	2	28.57143	22.65625
.82	7	0	0	.78125

THE BINOMIAL TEST SHOWS THAT .82 AND 1.59 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 1.186408

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE
PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

Material to be added to an e-Jacket

Reg. No. 66330-VV

1. Placement within the e-Jacket:

- [x] Default: chronological top
- [ ] Other: (PDF page number, i.e., "before page 45")

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2. Is this material:

- [ ] Newly accepted label (excluding Final Printed label)
- [ ] Notification
- [ ] New CSF

3. Attach this notice on top of the material. It must be clipped all together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Robert Westin

Phone: 7033055721 Division: RD/FB

Date: 1/18/06

E-Jackets are coming!

The march towards a paperless office continues with the conversion of paper regulatory files (Jackets) into e-Jackets. As of January 12, 2006, 19.2% of all regulatory files in the File Room have been converted into PDFs and are now available electronically in OPPIN (when you request a Jacket, click on the little red "E" button that will appear when your Jacket has been imaged and your Adobe Acrobat Reader will launch so you can view the e-Jacket). Once a Jacket has been converted into an e-Jacket and is available electronically, the paper Jacket is retired to the Federal Records Center.

How is new material added to an e-Jacket?

Once a Regulatory Jacket has been imaged and the paper Jacket has been archived (sent to the Federal Records Center), a new process has been established to add the new material to the e-Jacket. Just follow the instructions below.

To add material to an e-Jacket:

1. Collect the documents or material relating to a given Reg. No. and clip (NOT staple) the material together with the coversheet ("Material to be added to an e-Jacket"). Be sure to indicate if the material contains a new label, including a notification (but, excluding Final Printed Labels) or a revised CSF, such that there is information that needs to be captured by the Contractor for PPIS.

2. Give the material with the completed coversheet to the staff of the Information Services Center (Room 230).

3. The ISB staff will image the material and append it to the current PDF of the e-Jacket within one week. From then on, the material will be available electronically through the e-Jacket.

4. Once the material has been made a part of the e-Jacket, the hardcopy material will be archived in a batch accession.

ITRMD is planning e-Jacket demo sessions, which will be announced soon. Look for the announcement from the ITRMD Training Team to learn how easy it is to work with and use e-Jackets.

Contact Jeff Billingslea at 308-1838 if you have any questions.

ELECTRONIC JACKET

TABLE OF CONTENTS

EPA REGISTRATION NUMBER: 66330-UU

DECISION #: D219256
SUBMISSION #: S783743

DATE: Jan. 12, 2006

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 17 2006

James L. Platt
Project Manager
Arysta Lifescience NA Corp.
100 First Street, Suite 1700
San Francisco, CA 94105

Subject: Iodomethane Technical
EPA File Symbol Number 66330-UU
Storage Stability and Corrosion Characteristics Study

Dear Mr. Platt:

The Agency has completed the technical review of the Storage Stability (830.6317) and Corrosion Characteristics (830.6320) studies (MRID 466342-01) submitted in support of the registration of the subject product, and has concluded that these studies are acceptable. A copy of the Agency's Data Evaluation Review DP321565 dated November 28, 2005 is enclosed for your records.

The Agency's decision as to whether this product will be registered will be made upon completion of the review of other data submitted for this product.

If you have any questions, please contact Robert Westin by phone at (703) 305-5721 or via email at westin.robert@epa.gov.

Sincerely,

Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505C)

Enclosure

Date: November 28, 2005

SUBJECT: Iodomethane Technical

FROM: Debra Rate
Product Chemistry Team
Technical Review Branch/RD (7505C)

Debra N. Rate 11/28/05
SBr 11/28/05

TO: Mary Waller / Robert Westin RM 21
Fungicide Branch / RD (7505C)

DECISION NO: 219256
DP BARCODE: 321565
EPA REG. NO.: 66330-UU
PRODUCT: Iodomethane Technical
PCC: 000011
REGISTRANT: Arysta Lifescience North America Corporation
USE: Fungicide

INTRODUCTION:

The registrant has submitted the results of a 12 month storage stability and corrosions characteristics study, MRID No. 466342-01, for the subject product, Iodomethane Technical. The subject product contains iodomethane (99.8%) as the active Ingredient (AI). The Technical Review Branch (TRB) has been asked to review for acceptability the submitted data for the subject product.

SUMMARY OF FINDINGS

1. The current basic CSF (dated 22/JAN/2002) has a nominal concentration of 99.8% of the AI iodomethane. The nominal concentration does not concur with the label claim nominal concentration of 100%; however, when rounded to two significant figures, they are equal.

2. Reference guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) of the AI, iodomethane, in the subject product, were evaluated for 12 months in the dark at 25 ± 2°C. The time points for evaluation were 0, 3, 6, and 12 months. The test substance was stored both alone and in contact with 304 stainless steel coupons in amber glass jars with PTFE lined caps. Stainless steel was identified as the packaging material for storage and transport of the subject product. [MRID No. 466342-01]

3. The chemical stability of the AI was determined by the percent of the active ingredient measured in the test samples over the course of the one year study. The iodomethane analysis was determined using gas chromatography (GC) with flame ionization detection (FID). GC conditions are listed in the studies submitted with this data package. [MIRD No. 466342-01]

4. The steel coupons were visually evaluated for corrosion (discoloration, pits, cracks, etc.) The steel coupons were also evaluated for weight change and for corrosion rate. The test substance was evaluated visually for decomposition (discoloration, precipitation, phase separation, etc.). [MRID No. 466342-01]

5. The analytical results of the samples under study indicated that the % AI falls within the certified limits of the end-use product, as per the basic CSF (dated 22/JAN/2002). [MRID No. 466342-01]

6. The data submitted corresponding to the reference guideline 830.6317 (storage stability) and 830.6320 (corrosion characteristics) satisfy the data requirements of 40§CFR158.190. [MRID No. 466342-01]

7. All of the studies submitted in MRID No. 466342-01 have been completed in accordance with good laboratory practice (GLP). This satisfies the requirements of 40§CFR160.

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for the technical product, iodomethane and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup B, 830.6317 (storage stability) and 830.6320 (corrosion characteristics) are acceptable.

BARCODE No.: 321565 **File Symbol No.:** 66330-UU **PRODUCT NAME:** Iodomethane Technical

830.1800 Enforcement Analytical Method: [MRID No.466342-01]

The method used to determine the %AI, iodomethane, is gas chromatography (GC) with FID.

Reagents:
Iodomethane reference material, GLP characterized
Chloroform with 0.75% ethanol

Equipment and Operating Conditions:

Gas Chromatograph:	Hewlett-Packard gas chromatograph, HP5890 Series GC system with Series 7673 injector, controlled by personal computer.
Injector:	Split
Injector Temperature:	200°C
Carrier Gas:	Helium
Flow Rate:	14 psi
Septurm Purge Flow:	40 – 100 ml / min
Injection Volume:	1 µl

Flame ionization detector:

Detector Temperature:	250°C
Oven:	
Initial Temperature:	40°C (hold 4 min)
Ramp:	20°C / min
Final Temperature:	200°C (hold 1 min)
Capillary column:	Restek Rtx-624, 0.25 mm i.d., 1.4 µm film thickness, 30 m length

Usual laboratory glassware including pipettes, bottles, balances, etc.

830.6317(Storage Stability):

The test substance showed no signs of change during the study.

Time (months)	Results (%Iodomethane)	Average (%Iodomethane)
0 (initial)	99.3, 99.4, 100.4, 100.5	100.0 ± 0.8
3	100.5, 100.5, 99.8, 99.8,	100.2 ± 0.5
	100.2, 100.2, 100.0, 100.0	
6	99.9, 99.9, 99.9, 99.9,	99.9 ± 0.0
	99.8, 99.8, 99.9, 99.9	
12	100.4, 100.5, 101.7, 101.7	101.1 ± 0.8
	101.7, 101.8, 100.6, 100.7	

830.6320(Corrosion Characteristics)

Over the 12 month study, there was no significant weight change to any of the stainless steel coupons evaluated. There was no discernable corrosion of the stainless steel over the course of the study.

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 66330-UU

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Jean P. Jones

Phone: 305-7651 **Division:** 7B

Date: 5-22-06

Current as of Friday, February 10, 2006

Please file
66330-UU

Arysta LifeScience

March 28, 2006

Office of Pesticide Programs
Document Processing Desk
U.S. Environmental Protection Agency
Room 259, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

Attn: Mary Waller
Product Manager 21
(703) 308 9354

RE: Iodomethane - Authorization to discuss in Cancer Risk Assessment Forum.

Dear Mary:

Per John Kinzell's email of March 07, 2006 to Mike Metzger regarding this issue, please consider this letter Arysta LifeScience North America Corporation's formal authorization for the Agency to discuss Iodomethane in the Cancer Risk Assessment Forum.

Should you have any questions, please contact me at (415) 279 6031.

Thank you and best regards,

Laurent C. Mézin, Ph.D.
Consulting Regulatory Manager
Arysta LifeScience North America
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Cary, NC 27513
415 279 6031